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PATENT & TRADEMARK OFFICE

January 16, 2007

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Conf. No.: 8452
Art Unit: 1631
Examiner: R.S. Negin

Re: U.S. Patent Application No. 09/404,520 filed September 23, 1999
Inventors: Yongwei CAO *et al.*
Title: Emericella Nidulans Genome Sequence on Computer Readable Medium and Uses Thereof
Atty. Dkt: 16517.081

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appeal Brief under 37 C.F.R. § 41.37; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Authorization is hereby given to charge $500.00 for filing an Appeal Brief to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.081. A duplicate copy of this letter is enclosed.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.081. A duplicate copy of this letter is attached.

Respectfully submitted,

Thomas E. Holsten

Enclosures

Thomas E. Holsten (Reg. No. 46,098)

JAN 16 2007
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	Confirmation No.: 8452
Yongwei CAO *et al.*	Art Unit: 1631
Appln. No.: 09/404,520	Examiner: R.S. Negin
Filed: September 23, 1999	Atty. Docket: 16517.081

For: **Emericella Nidulans Genome Sequence on Computer Readable Medium and Uses Thereof**

APPELLANT'S BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on November 14, 2006. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Appellant identified the following decision by the Board of Patent Appeals and Interferences which may be related to the instant appeal: Appeal No. 2005-2746 (Application No. 09/404,520), mailed March 16, 2006, a copy of which is provided in the attached Related Appeals Appendix.

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3. Status of Claims

Claims 58-79 are pending. Claims 1-57 have been cancelled without prejudice to or disclaimer of the subject matter claimed therein. Claims 58-79 stand finally rejected for *res judicata* and under 35 U.S.C. § 103. Appellant appeals all of the rejections of claims 58-79.

4. Status of Amendments

Appellant has not filed any amendments to the claims subsequent to Final Rejection in this case.

5. Summary of the Claimed Subject Matter

Independent Claim 58: The claimed subject matter of independent claim 58 is directed to a method of identifying a nucleotide sequence comprising comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequence selected from the group consisting of SEQ ID NO: 16207 through 27905 and complements thereof, and identifying the target sequence as being present in the computer readable medium, where the target sequence is compared to at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905. Specification at page 34, lines 3-20 and pages 37, line 1 through page 39, line 20.

Independent Claim 59: The claimed subject matter of independent claim 59 is directed to a method for identifying a nucleic acid sequence comprising providing a target nucleotide sequence, comparing the target nucleotide sequence to one or more nucleotide sequences stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof where the target nucleotide sequence is compared to at least one of the sequence selected from the

group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905, and identifying the target nucleotide sequence as having significant sequence identity to the one or more nucleotide sequences stored in a computer readable medium based on the comparison. Specification at page 34, lines 3-20 and pages 37, line 1 through page 39, line 20.

Independent Claim 67: The claimed subject matter of independent claim 67 is directed to a method of detecting a nucleotide sequence comprising, providing a target nucleotide sequence, comparing the target nucleotide sequence to a nucleotide sequence stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof where the target nucleotide sequence is compared to at least one of the sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905, and identifying the target sequence as homologous to the nucleotide sequence based on the comparison. Specification at page 34, lines 3-20 and pages 37, line 1 through page 39, line 20.

Independent Claim 71: The claimed subject matter of independent claim 71 is directed to a method of ranking a target nucleotide sequence by homology to a nucleotide sequence of *E. nidulans* comprising, providing a target nucleotide sequence, comparing the target nucleotide sequence to a nucleotide sequence stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof where the target nucleotide sequence is compared to at least one of the sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905, and ranking the target sequence by degree of homology to the nucleotide sequence of *E. nidulans*. Specification at page 34, lines 3-20 and pages 37, line 1 through page 39, line 20.

Independent Claim 73: The claimed subject matter of independent claim 73 is directed to method for identifying a nucleic acid sequence comprising providing a target nucleotide sequence comparing the target nucleotide sequence to one or more nucleotide sequences stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof where the target nucleotide sequence is compared to at least one of the sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905; and identifying the target nucleotide sequence as having significant sequence identity to the one or more nucleotide sequences stored in a computer readable medium, where the sequences stored in the computer readable medium function to facilitate the identification of the target sequence as having significant sequence identity. Specification at page 28, lines 5-16, and page 37, line 6 through page 40, line 2.

Independent Claim 79: The claimed subject matter of independent claim 79 is directed to a method for identifying the function of a plurality of fungal nucleic acid sequences by determining homology to a nucleotide sequence in the *Emericella nidulans* genome comprising providing a plurality of target fungal nucleotide sequences; comparing the target fungal nucleotide sequences to one or more *E. nidulans* nucleotide sequences stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and descriptions identifying encoded proteins where the target fungal nucleotide sequence is compared to at least one of the sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905; and identifying the function of the target nucleotide sequence based on homology to a nucleotide sequence in the *E. nidulans* genome based on said comparison, where said sequences are stored in said computer readable medium function to facilitate the

identification. Specification at page 28, lines 5-16, and page 37, line 6 through page 40, line 2.

6. Grounds of Rejection to be Reviewed on Appeal

The issues in this Appeal are:

(a) whether claims 58-79 are unpatentable for *res judicata* in view the Board's decision mailed March 16, 2006;

(b) whether claims 58-79 are unpatentable under 35 U.S.C. §103(a), as allegedly being obvious over Rodriguez-Tome *et al.*

7. Argument

A. Summary of Appellant's Position

As the amended claims differ from the previously appealed claims, the rejection of the claims under *res judicata* is improper. The previously appealed claims did not recited that the target sequence was compared to at least one of the sequence of SEQ ID NO: 16207 to 27905. As such, the amended claims were not the subject of the Board's previous decision and can not be rejected under the doctrine of *res judicata* because of the difference in claimed subject matte.

Furthermore, the claims, as a whole, are directed to methods of identifying, detecting and ranking nucleic acid sequences, and as such are directed to a functional application where a target sequence is compared to at least one of the sequences in the group of SEQ ID NO: 16207 to 27905. Such stored sequence facilitate the claimed methods and are therefore function descriptive matter and must be included in the obviousness determination. Moreover, the claimed methods are not taught or suggested in the cited references. As such, the claims are not obvious.

B. The Amended Claims Are Not Subject to the Board's Previous Decision

The Examiner alleges that "the amendments made to the set of claims filed on May 16, 2006 are still governed by the decision of the Board of Patent Appeals and Interferences decision of March 16, 2006." Final Action at page 2.

To properly establish *res judicata* the Examiner must show that there is an identity of issues presented for adjudication and the issues previously decided. *In re Katz*, 467 F.2d 939, 942, 167 U.S.P.Q. 487 (C.C.P.A. 1970). The Manual of Patent Examining Procedures provides that the courts have "materially restricted the use a *res judicata* rejections." MPEP § 706.03(w), 8th Ed., rev 5. August 2006. The Examiner states that a submission filed with a request for continued examination (RCE) "containing arguments without either an amendment of the rejected claims or the submission of a showing of facts will not be effective to remove such rejection." Final Action at page 2.

In the present application, Appellants filed a timely request for continued examination under 37 CFR 1.114. *See, e.g.* Final Action at page 2. The RCE included an amendment to the independent claims to recite, *inter alia*, that the "target nucleotide sequence is compared to at least one of said sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905" as well as including new independent claims 73 and 79. *See, e.g.*, Amendment filed May 16, 2006. In the Board's previous decision, the Board interpreted representative claim 58 to be "directed to a method that comprises comparing a target sequence to a database of at least 100 nucleotide sequences, at least one of which is included in the group of sequences represented by SEQ ID NO: 16207 to 27905." Board Decision mailed March 16, 2006. The claims appealed in that appeal did not contain the phrase as included in the amended claims filed with the RCE. The Board did not consider such claim language in its Decision. Nor did the Board consider claims directed to the identification of the function of a plurality of fungal nucleic acid sequences as claimed in independent claim 79.

The Examiner, however, broadly states that "the arguments and amendments to the claims made on May 16, 2006, can be addressed using the Board of Patent Appeals and Interferences decision of March 16, 2006." Final Action at pages 2-3. The Examiner provides no support for this assertion. Moreover, the Board did not base its decision on the target sequence being compared to at least one of the sequences of SEQ ID NO: 16207 to 27905. Instead, as suggested by the Board's claim interpretation of claim 58, the target sequence was compared to a database of at least 100 nucleotide sequences, at least one of which is included in this group.

As the Board did not base its decision on the amended claims, the *res judicata* rejection is improper and should be reversed.

C. The Claimed Methods are Not Obvious

Claims 58-79 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rodriguez-Tome *et al.* (Nucl. Acids Res., vol. 24, pp. 6-12, 1996). Final Action at pages 3-4. This rejection is respectfully traversed for at least the reasons which follow.

The Examiner argues that "Rodriguez-Tome et al. teach CD-ROM with [sic] containing EMBL nucleotide sequence database." *Id.* at page 3. The Examiner further argues that the cited reference further teaches "that the CD-ROM also contains software for data query and retrieval," and "comparing users' sequences to sequence in the EMBL nucleotide sequence database." *Id.*

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed

combination must be found in the prior art, and not be based on Applicant's disclosure. *See* M.P.E.P. §§2143.01 and 2143.03.

In a proper obviousness determination, the changes from the prior art must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the claimed invention. *See In re Chu,* 36 U.S.P.Q.2d 1089, 1094 (Fed. Cir. 1995). This includes what could be characterized as simple changes. *See, e.g., In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984) (Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.).

Only when the prior art teaches or suggests the claimed invention does the burden fall on the applicant to rebut that *prima facie* case. *See In re Dillon,* 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990) (in banc), *cert. denied,* 500 U.S. 904 (1991). However, a *prima facie* case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.

The present invention is drawn to methods of identifying, detecting and ranking nucleic acid sequences comprising, *inter alia*, comparing target nucleotide sequences to one or more nucleotide sequences stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, where the target sequence is compared to at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905.

(1) The Recited Sequences Are Functional Descriptive Matter

All claim limitations must be considered when determining patentability. *See, In re Gulack*, 703 F.2d 1381, 1385, 217 U.S.P.Q. 401 (Fed. Cir. 1983). "Differences

between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter." *Id.* at 1385. The Federal Circuit has held that "printed matter cases have no factual relevance where the invention as defined by the claims requires that the information be processed not by the mind but by a machine, the computer." *In re Lowry*, 32 F.3d 1579, 1583, 32 U.S.P.Q.2d 1031 (Fed. Cir. 1994) (internal quotes omitted).

The sequences stored on a computer readable medium, when read in light of the claims as a whole, exhibit the requisite functional relationship. The appealed claims are directed to methods of identifying, detecting or ranking a nucleotide sequence comprising, *inter alia*, comparing a target sequence to a sequence stored in computer readable medium where the target sequence is compared to at least one of the sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905. The sequences stored on computer readable medium are utilized in the act of comparing and thus greatly facilitate the identification, detection or ranking of nucleotide sequences from *E. nidulans* within the sequences stored on computer readable medium. As such, they cannot be ignored as non-functional, descriptive material in the obviousness determination.

The sequences stored on a computer readable medium, when read in light of the claims as a whole, exhibit the requisite functional relationship and accordingly should be considered in determining patentability. The amended claims are directed to methods of identifying, detecting or ranking a nucleotide sequence comprising, *inter alia*, comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, where the identification, detection, or ranking of the target sequence is based on a comparison with at least one of the sequences SEQ ID NO: 16207 through SEQ ID NO:

27905. The sequences stored on computer readable medium are utilized in the act of comparing and thus greatly facilitate the identification, detection or ranking of nucleotide sequences by comparing them to sequences from *E. nidulans*. As such, they cannot be ignored as non-functional, descriptive material in the obviousness determination.

The claimed methods would not achieve their purposes (identification, detection or ranking) without the comparison to at least one of the recited SEQ ID NOs recorded on a computer readable medium. As previously argued, the claimed methods allow for the easy identification, ranking or detection of nucleotide sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

As such, the sequences are functionally related to the computer readable medium and therefore must be considered for the obviousness determination.

(2) Rodriguez-Tome does not teach or suggest all of the elements

The Examiner asserts that Rodriguez-Tome *et al.* teach a CD-ROM having EMBL nucleotide sequences, as well as software for data query. Final Action at pages 10-11. The Examiner further alleges that Rodriguez-Tome *et al.* further teaches "comparing users' sequences (=target sequences) to sequence in the EMBL nucleotide sequence database." *Id.* at page 11. However, whatever else Rodriguez-Tome *et al.* discloses or suggests, it does not disclose or suggest a method for identifying, detecting, and ranking sequences by comparing a target sequence to at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905.

The Examiner has provided no evidence that Rodriguez-Tome *et al.* teaches or suggests any of the sequences of SEQ ID NO: 16207 through SEQ ID NO: 27905. Indeed, both the Board and the Examiner have acknowledged that Rodriguez-Tome *et al.* does not teach any of the sequences of SEQ ID NOs: 16207 through 27905. *See, e.g.*, Board Decision at page 3. As the specification discloses, the sequences are isolated from

the filamentous fungus *Emericella nidulans*, which is frequently used as a model eukaryotic organism to investigate a variety of biological mechanisms. *See,* specification at page 2, lines 5-10. By employing the claimed methods, the skilled artisan can identify, rank or detect homologous sequences in the *E. nidulans* genome for use in identifying gene function or transcription profiling through the comparison of target sequences to at least one sequence selected from SEQ ID NO: 16207 through SEQ ID NO: 27905. The skilled artisan can also identify the function of a plurality of fungal sequences using such methods.

The Examiner has alleged that it "would have been *prima facie* obvious to one of ordinary skill in the art to have used a computer system comprising a CD-ROM of Rodriguez-Tome et al. to perform sequence searches against a collection of sequence data. Final Action at page 11. The Examiner asserts that the ordinary practitioner would have been motivated because using CD-ROM databases would make database searches "accessible to clients without Internet Access." *Id.*

The mere fact that references can be modified does not render the resultant modification obvious unless the prior art also suggests the desirability of the modification. M.P.E.P. § 2143.01; *In re Mills,* 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990); *see also, In re Fritch,* 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). This includes what could be characterized as simple changes. *See Gordon*, 221 U.S.P.Q. at 1127. Even changes that are allegedly "merely a matter of engineering design choice" require a suggestion of desirability in the prior art. *See In re Kuhle*, 188 U.S.P.Q. 7, 9 (CCPA 1975). In *Kuhle*, the element in question as the "obvious matter of design choice" was obvious because it was "notoriously old with the common flashlight." *Id.* at 8. As such, the prior art did contain a teaching that suggested the modification in question to one of ordinary skill in the art, thereby establishing a *prima facie* case of obviousness.

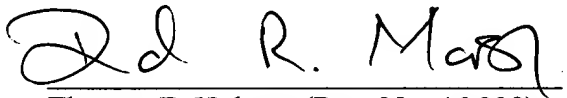
In the present case, the deficiencies in the teachings of Rodriguez-Tome *et al.* regarding the nucleotide sequence stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof are not compensated for by any other reference. As such, Rodriguez-Tome *et al.* does not provide specific motivation to one of ordinary skill in the art such that the skilled artisan would arrive at the present invention upon reading Rodriguez-Tome *et al.*

In sum, the Examiner's conclusion of obviousness is based on improper hindsight reasoning. No suggestion to modify the cited reference has been found in the cited reference or pointed out to Appellant from the general knowledge of one of ordinary skill in the art. For at least these reasons, the Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, as required by 35 U.S.C. § 103. As such, the rejection of claims 58-79 is improper and should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



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Monsanto Company

CLAIMS APPENDIX

58. A method of identifying a nucleotide sequence comprising comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, and identifying said target sequence as being present in the computer readable medium based on said comparison, wherein said target sequence is compared to at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905.

59. A method for identifying a nucleic acid sequence comprising:

a) providing a target nucleotide sequence;

b) comparing said target nucleotide sequence to one or more nucleotide sequences stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof wherein said target nucleotide sequence is compared to at least one of said sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905; and

c) identifying said target nucleotide sequence as having significant sequence identity to said one or more nucleotide sequences stored in a computer readable medium based on said comparison.

60. The method according to claim 59, wherein said target sequence shares between 100% and 90% sequence identity with one or more of said nucleotide sequences stored on a computer readable medium.

61. The method according to claim 60, wherein said target sequence shares between 100% and 95% sequence identity with one or more of said nucleotide sequences stored on a computer readable medium.

62. The method according to claim 61 wherein said target sequence shares between 100% and 98% sequence identity with one or more of said nucleotide sequences stored on a computer readable medium.

63. The method according to claim 62 wherein said target sequence shares between 100% and 99% sequence identity with one or more of said nucleotide sequences stored on a computer readable medium.

64. The method according to claim 59, wherein said target sequence is identified as homologous to an open reading frame (ORF) within said nucleotide sequence stored on a computer readable medium.

65. The method of claim 59, wherein said target sequence is a nucleotide sequence of between about 30 and about 300 nucleotide residues in length.

66. The method of claim 59, wherein said target sequence is identified as homologous to a sequence encoding an *Emericella nidulans* protein or fragment thereof within said one or m ore nucleotide sequences stored on a computer readable medium.

67. A method of detecting a nucleotide sequence comprising:

a) providing a target nucleotide sequence;

b) comparing said target nucleotide sequence to a nucleotide sequence stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, wherein said target sequence is compared to at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905; and

c) identifying said target sequence as homologous to said nucleotide sequence based on said comparison.

68. The method according to claim 67, wherein said target sequence is homologous to an open reading frame (ORF) within said nucleotide sequence.

69. The method of claim 67, wherein said target sequence is a nucleotide sequence of between about 30 and about 300 nucleotide residues in length.

70. The method of claim 67, wherein said target sequence is identified according to degree of homology to said nucleotide sequence stored in a computer readable medium.

71. A method of ranking a target nucleotide sequence by homology to a nucleotide sequence of *E. nidulans* comprising:

a) providing a target nucleotide sequence;

b) comparing said target nucleotide sequence to a nucleotide sequence stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through

SEQ ID NO: 27905 and complements thereof wherein said target nucleotide sequence is compared to at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905; and

c) ranking said target sequence based on percent homology to said nucleotide sequence of *E. nidulans*.

72. The method of claim 71, wherein said target sequence is a nucleotide sequence of between about 30 and about 300 nucleotide residues in length.

73. A method for identifying a nucleic acid sequence comprising:

a) providing a target nucleotide sequence;

b) comparing said target nucleotide sequence to one or more nucleotide sequences stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof wherein said target nucleotide sequence is compared to at least one of said sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905; and

c) identifying said target nucleotide sequence as having significant sequence identity to said one or more nucleotide sequences stored in a computer readable medium, wherein said sequences stored in said computer readable medium function to facilitate said identification of said target sequence as having significant sequence identity.

74. The method of claim 73, wherein said method identifies a nucleic acid sequence within the *Emericella nidulans* genome.

75. The method of claim 73, wherein said target sequence shares between 100% and 90% sequence identity with one or more of said sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905.

76. The method of claim 75, wherein said target sequence shares between 100% and 95% sequence identity with one or more of said sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905.

77. The method of claim 76, wherein said target sequence shares between 100% and 98% sequence identity with one or more of said sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905.

78. The method of claim 77, wherein said target sequence shares between 100% and 98% sequence identity with one or more of said sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905.

79. A method for identifying the function of a plurality of fungal nucleic acid sequences by determining homology to a nucleotide sequence in the Emericella nidulans genome comprising:

a) providing a plurality of target fungal nucleotide sequences;

b) comparing said target fungal nucleotide sequences to one or more E. nidulans nucleotide sequences stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and descriptions identifying encoded proteins wherein said target fungal nucleotide sequence is compared

to at least one of said sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905; and

c) identifying the function of said target nucleotide sequence based on homology to a nucleotide sequence in the E. nidulans genome based on said comparison, wherein said sequences are stored in said computer readable medium function to facilitate said identification.

EVIDENCE APPENDIX

None

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RELATED PROCEEDINGS APPENDIX

Board of Patent Appeals and Interferences Appeal No. 2005-2746 (Application No. 09/404,520).

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16517.081 TEH

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

In-house (TEK) (15498) A/US

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YONGWEI CAO, AZITA GHODSSI, GREGORY J. HINKLE, JAMES D. McININCH, WILLIAM E. TIMBERLAKE, and JAEHYUK YU

MAILED MAR 16 2006 U.S. PATENT AND TRADEMARK OFFICE

Docketed CAFC Appeal
Due Date 5-16-06
Initial VB

Appeal No. 2005-2746
Application No. 09/404,520

HEARD December 15, 2005

Before SCHEINER, GRIMES, and ADAMS, Administrative Patent Judges.

Opinion by GRIMES, Administrative Patent Judge.
Dissenting opinion by ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a method of determining whether a target nucleic acid is similar to other, specified nucleic acids. The examiner has rejected the claims as obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 134. We conclude that the obviousness of the claimed method does not depend on which sequences are being compared. We therefore affirm the rejection.

ENTERED 3/24/06 mmd

Background

The specification discloses "nucleic acid molecules representing the genome of the filamentous fungus, Emericella nidulans (previously and still sometimes called

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Aspergillus nidulans) and, in particular, to nucleic acid sequences corresponding to genes, promoters, other regulatory elements, and introns found in the E. nidulans genome." Page 1. "The nucleic acid sequences disclosed . . . are believed to represent substantially all, or at least a major part, of the genes in the E. nidulans genome." Page 3. One "aspect of th[e] invention comprises a set of about 12,000 genes or partial genes of the E. nidulans genome including genes represented by SEQ ID NO: 16207 through SEQ ID NO: 27905." Page 4.

The specification also "provides computer readable media having recorded thereon one or more of the nucleotide sequences provided by this invention and methods for using such media, e.g., in searching to identify genes associated with nucleic acid sequences." Page 6. See also page 39:

> [T]he computer-based systems of the present invention comprise a data storage means having stored therein a nucleotide sequence of the present invention and the necessary hardware means and software means for supporting and implementing a search means. . . . Search means are used to identify fragments or regions of the sequence of the present invention that match a particular target sequence or target motif. A variety of known algorithms are disclosed publicly and a variety of commercially available software for conducting search means are available [and] can be used in the computer-based systems of the present invention. Examples of such software include, but are not limited to, MacPattern (EMBL), BLASTIN and BLASTIX (NCBIA).

Discussion

1. Claim construction

Claims 58-72 are pending and stand rejected. The claims will stand or fall together, because Appellants did not argue them separately in the Appeal Brief. See (then-applicable) 37 CFR § 1.192(c)(7). We will focus on claim 58, which is representative and reads as follows:

58. A method of identifying a nucleotide sequence comprising comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, and identifying said target sequence as being present in the computer readable medium.

Thus, claim 58 is directed to a method that comprises comparing a target sequence to a database of at least 100 nucleotide sequences, at least one of which is included in the group of sequences represented by SEQ ID NOs 16207 to 27905. The method implicitly requires that computer hardware and software carry out the comparison, because the nucleotide sequences must be recorded on a computer-readable medium.

2. Obviousness

The examiner rejected claims 58-72 under 35 U.S.C. § 103 on the basis that the claimed subject matter would have been obvious in view of Rodriguez-Tomé.[1] The examiner characterized Rodriguez-Tomé as teaching most of the limitations of claim 58. See the Examiner's Answer, page 5. The examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905, but she concluded that the specific sequences recited in the claim represent merely nonfunctional descriptive material and therefore do not patentably distinguish the claimed method from the method of the prior art. See id., pages 6-7.

Appellants have not disputed that Rodriguez-Tomé teaches a method comprising comparing a target nucleotide sequence to a database comprising at least 100

[1] Rodriguez-Tomé et al., "The European Bioinformatics Institute (EBI) databases," Nucleic Acids Research, Vol. 24, pp. 6-12 (1996).

nucleotide sequences and identifying the target sequence as being present in the database. These limitations reasonably appear to be met by Rodriguez-Tomé. See, e.g., page 6, the paragraph bridging the columns (EMBL nucleotide sequence database, release 44, contained 506,192 entries) and page 10, section headed "Sequence search facilities" ("The EBI provides a number of services that allow users to compare their own sequences against the most currently available data in the EMBL nucleotide sequence database.").

Appellants argue, however, that the sequences recited in the claims are functional: "The sequences stored on computer readable medium are utilized in the act of comparing and thus greatly facilitate the identification, detection or ranking of nucleotide sequences within the sequences stored on computer readable medium. As such, they cannot be ignored as non-functional, descriptive material in the obviousness determination." Reply Brief, pages 3-4. "The claimed methods would not achieve their purposes (identification, detection or ranking) without the sequences recorded on a computer readable medium. . . . As such, the sequences are functionally related to the computer readable medium and therefore must be considered in the obviousness determination." Id., page 4. Appellants conclude that, since the reference does not teach the recited sequences, it does not teach or suggest all of the elements of the claimed method and therefore does not support a prima facie case of obviousness. See, e.g., the Appeal Brief, pages 21-22.

Thus, the only issue in dispute seems to be whether the specific sequences recited in claim 58 distinguish the claimed method from known methods that used other sequences. The examiner argues that the sequences are nonfunctional descriptive

material and therefore entitled to no patentable weight; Appellants argue that the sequences are functional and therefore distinguish the claimed method from the prior art.

The distinction between functional and nonfunctional descriptive material arises out of cases dealing with printed matter limitations. For example, in In re Gulack, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983), printed matter that was functionally related to its substrate was held to distinguish the claimed product from the prior art. In Gulack, the claims "recite[d] three key elements: (1) a band . . .; (2) a plurality of individual digits imprinted on the band or ring at regularly spaced intervals; and (3) an algorithm by which the appropriate digits are developed." Id. at 1382, 217 USPQ at 402. With the digits generated by the algorithm printed on it, the band could be used "to perform magic tricks or to display various aspects of number theory." Id. at 1383, 217 USPQ at 402. The claims had been rejected as obvious, based on prior art that differed only in what was printed on the band. Id. at 1384, 217 USPQ at 403.

The court stated that, although limitations reciting printed matter cannot be ignored, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight." Id. at 1385, 217 USPQ at 404 (footnote omitted). The court stated that "the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate." Id. at 1387, 217 USPQ at 404. The Gulack court held that such a relationship had been shown; i.e., the looped structure of the substrate and the particular digits printed on it interrelated to give the

claimed product a property it would not have had if either the structure or the digits were changed. Therefore, the content of the printed matter was held to produce a nonobvious difference between the claimed product and the prior art.

By contrast, in In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004), a printed matter limitation was held to be nonfunctional and therefore inadequate to distinguish the claimed product from the prior art. Ngai claimed a kit that contained at least one of several reagents (e.g., buffer) and instructions that described a process of using the reagents to amplify RNA. Id. at 1337, 70 USPQ2d at 1863. The claim had been rejected based on prior art that disclosed a kit containing buffer and instructions, albeit instructions that described a different process. Id. at 1337, 70 USPQ2d at 1863.

The Ngai court held that the printed instructions were not related to the claimed kit in the way that Gulack's numbers were related to his band. See id. at 1339, 70 USPQ2d at 1864: "In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product." The rejection was affirmed.

A similar distinction has been recognized in the context of computer-related inventions. Compare, for example, In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994), with In re Warmerdam, 33 F.3d 1354, 31 USPQ2d 1754 (Fed. Cir. 1994).[2]

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[2] We recognize that the Lowry court stated that "[t]he printed matter cases have no factual relevance where 'the invention as defined by the claims requires that the information be processed not by the mind but by a machine, the computer.'" 32 F.3d at 1584, 32 USPQ2d at 1034. This statement, however, must be regarded as dictum, because the court went on to conclude that the data structures at issue in Lowry were not analogous to printed matter. See id. Thus, the court's statement regarding the relevance of the

Both cases involved so-called "data structures". The court in Lowry concluded that the data structures were "physical entities that provide increased efficiency in computer operation" and were not analogous to printed matter. 32 F.3d at 1584, 32 USPQ2d at 1035. The Warmerdam court, however, concluded that the "data structure" claimed therein was not a physical arrangement of hardware but instead was "nothing more than another way of describing the manipulation of ideas contained in" other claims and therefore not statutory subject matter eligible for patenting. 33 F.3d at 1362, 31 USPQ2d at 1760.

Here, the descriptive material (SEQ ID NOs) recited in claim 58 is not functional material like the data structures in Lowry. Those data structures, "while including data resident in a database, depend only functionally on information content. While the information content affects the exact sequence of bits stored in accordance with Lowry's data structures, the claims require specific electronic structural elements which impart a physical organization on the information stored in memory." 32 F.3d at 1583, 32 USPQ2d at 1034. As a result, Lowry's data structures "provide increased efficiency in computer operation. They are not analogous to printed matter." Id. at 1584, 32 USPQ2d at 1035.

In this case, by contrast, there is no evidence that SEQ ID NOs 16207 to 27905 functionally affect the process of comparing a target sequence to a database. There is no evidence, for example, that these SEQ ID NOs interact with other computer hardware or software to affect the efficiency or accuracy or any other characteristic of

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printed matter cases to inventions involving computer-readable information was not essential to the holding. The Lowry court did not consider whether, and under what circumstances, computer-readable information that is analogous to printed matter can distinguish a claimed invention from the prior art.

the comparison. Rather, the SEQ ID NOs appear to be used merely as inputs for a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database. In other words, the specific SEQ ID NOs recited in the claims do not affect how the method of the prior art is performed – the method reasonably appears to be carried out the same way regardless of which specific sequences are included in the database.[3]

Thus, the descriptive material in this case is properly considered to be nonfunctional. The SEQ ID NOs recited in claim 58 are analogous to the instructions in In re Ngai. The Ngai court held that, in contrast to Gulack, the printed instructions were not functionally related to the claimed kit. See id. at 1339, 70 USPQ2d at 1864: "In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter." The same is true here: the recited sequences are not functionally related to the computer system carrying out the comparison because the computer compares a target sequence to a database the same way regardless of whether the database includes any of SEQ ID NOs 16207 to 27905: the SEQ ID NOs and the computer do not depend on each other for their function.

The Ngai court also stated that "[i]f we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction

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[3] Of course, the results of comparing a target sequence to a database may change depending on which sequences are included in the database. That possibility does not mean that the database sequences are functional: MP3 files encoding "America the Beautiful" and "Yankee Doodle Dandy," respectively, will cause a computer's speaker to output different songs, yet music is a paradigmatic nonfunctional

sheet to the product. . . . Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product." Id. at 1339, 70 USPQ2d at 1864.

Similarly here, if we were to adopt Appellants' position, anyone could continue patenting methods of analyzing genetic sequence data – or any other data, for that matter – provided that they included at least one new DNA sequence or other datum in a known database. Appellants have discovered what are apparently several thousand new DNA sequences from E. nidulans. They are entitled to patent the DNAs having those sequences (assuming the DNAs meet all of the statutory requirements) but they are not entitled to patent a known method of sequence comparison by merely including at least one novel DNA sequence in a database.

Our conclusion is consistent with the USPTO's recently announced examination guidelines relating to subject matter eligible for patenting. See Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 Off. Gaz. Pat. Office 142 (November 22, 2005), especially pages 151-152. (The Manual of Patent Examining Procedure includes substantively the same guidance. See MPEP, 8th edition (revised Aug. 2005), § 2106(IV)(B)(1).)

The Patent Subject Matter Eligibility Interim Guidelines state that "'functional descriptive material' consists of data structures and computer programs which impart functionality when employed as a computer component. . . . 'Nonfunctional descriptive

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descriptive material. Thus, descriptive material is not functional merely because it results in different outputs when acted on by a computer program.

material' includes but is not limited to music, literary works and a compilation or mere arrangement of data." Page 151. When claims comprise nonfunctional descriptive material recorded on computer-readable media, the guidelines direct the examiner to

> determine whether the claimed nonfunctional descriptive material be given patentable weight. The USPTO must consider all claim limitations when determining patentability of an invention over the prior art. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). The USPTO may not disregard claim limitations comprised of printed matter. See Gulack, 703 F.2d at 1384, 217 USPQ at 403; see also Diehr, 450 U.S. at 191, 209 USPQ at 10. However, the examiner need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

Pages 151-152.

Consistent with the Guidelines, the examiner in this case considered all of the limitations of the claims but declined to give patentable weight to those limitations reciting nonfunctional descriptive material; specifically, SEQ ID NOs 16207 to 27905.

Finally, a couple of points in the dissent require a response. Our dissenting colleague argues that the claimed method is analogous to a hybridization assay using nucleic acids having the sequences shown in SEQ ID NOs 16207 through 27905. He reasons that if Appellants were claiming such an assay, using actual nucleic acid molecules, the novelty of the nucleic acids would have to be considered in determining the obviousness of the method.

The short answer to that hypothetical is that Appellants are not claiming a hybridization assay, they are claiming a computer-implemented method of comparing two sets of data. The comparison seems to call for a more detailed rebuttal, though. It may seem implausible to compare a computer-based calculation and a hybridization

assay, but both approaches are ways of determining the degree of similarity between nucleic acids. Why would the structure of the nucleic acids be a factor in the obviousness analysis, when the sequences of the SEQ ID NOs is not?

The reason the dissent's hybridization method is treated differently from the claimed method comes down to the difference between chemical compounds and chemical formulas. A hybridization method combines two physical compounds and observes their interaction to determine their similarity. The claimed method reduces the nucleic acids to abstract representations of their structure (i.e., sequences of letters representing the structure of the nucleic acids) and then mathematically calculates the degree of similarity between those abstractions and another abstraction representing the structure of a target nucleic acid.

It is the reduction of the physical nucleic acids to an abstract representation of their structure that distinguishes the claimed method from the dissent's hybridization assay. When a physical object is used in a method, the obviousness of the method depends in part on the novelty of the object used – if an object was previously unknown, it can hardly be said that using that unknown object would have been obvious, even in an otherwise old method. Cf. In re Ochiai, 71 F.3d 1565, 1569, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995).

However, when instead the method merely manipulates data, the obviousness or nonobviousness of the method does not depend on whether the particular set of data was novel: given a known method of comparing data representing, e.g., nucleic acid structures, it would be obvious to use that method to compare any two sets of data representing nucleic acid structures, even if a particular sequence of As, Gs, Cs, and Ts

had not previously been compared to other sequences of As, Gs, Cs, and Ts. Thus, a difference only in nonfunctional descriptive material, such as data representing nucleic acids, does not make a claimed process nonobvious over a process, known in the prior art, that is otherwise identical.

This brings us to a second point on which we disagree with the dissent's analysis. The dissent argues that the SEQ ID NOs recited in claim 58 are functional descriptive material because they might change the result obtained when a target sequence is compared to the sequences in the database.[4]

We do not agree with this reasoning. As noted above (footnote 3), when music is recorded on a computer-readable medium, the sound that is output through the computer's speakers, when the music is read by an appropriate program, will depend on the specific sequence of notes that is recorded. Music, however, is widely considered to be ineligible for patent protection.[5]

Thus, descriptive material is not functional merely because it can change the output that results when a computer program reads the material from a medium. If affecting the output made descriptive material functional, then a compact disk with a song recorded on it could be patented. See the Interim Guidelines, page 151: "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in

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[4] The dissent says they "will" change the results but this is true only if the target sequence is one of SEQ ID NOs 16207 through 27905: if the target sequence matches some other sequence in the database – or none at all – the result will be the same whether or not the database includes any of SEQ ID NOs 16207 through 27905.

[5] The passage from the Interim Guidelines cited by the dissent is not to the contrary. In the cited example, the nonfunctional descriptive material (musical notes) is apparently read by the computer program as a signal to play "another defined series of notes." In the instant claims, by contrast, the data

most cases." That result is clearly contrary to the prevailing interpretation of 35 U.S.C. § 101, and supports our conclusion that data that do nothing more than change the output of a computer program that read them are nonfunctional descriptive material.

Summary

The examiner's analysis and conclusion are consistent with the USPTO's examination guidelines and with the relevant case law. We therefore affirm the examiner's rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

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(SEQ ID NOs) are merely used as inputs for comparison to a target sequence, not as functional signals to a computer program.

ADAMS, Administrative Patent Judge, dissenting.

I disagree with the majority's characterization of the sequences recited in appellants' claimed invention as non-functional descriptive material (supra, page 8). I also disagree with the majority's assertion (supra, page 1), "the obviousness of the claimed method does not depend on which sequences are being compared." In my opinion, the claimed methods require the specifically recited sequences, which are functionally related to the remaining elements of the claimed invention. Accordingly, I respectfully dissent.

I. Appellants' claimed method:

The claims before us on appeal are method claims. The majority limited their analysis to appellants' claim 58; accordingly, I focus my attention on claim 58. In this regard, I recognize the majority's construction of claim 58. Supra, pages 2-3. According to the majority (supra, page 3), "claim 58 is directed to a method that comprises comparing a target sequence to a database of at least 100 nucleotide sequences, at least one of which is included in the group of sequences represented by SEQ ID NOs 16207 to 27905." The majority fails to recognize, however, that the method of claim 58 requires as a final step, "identifying said target sequence as being present in the computer readable medium." Accordingly, I disagree with the majority's construction of the claimed invention. As set forth in In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403 (Fed. Cir. 1983), the PTO must consider all claim limitations when determining patentability of an invention over the prior art – "the claim must be read as a whole." Accord In re Ochiai, 71 F.3d 1565, 1569, 37 USPQ2d 1127, 1131 (Fed. Cir.

1995) ("The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'"). Therefore, I offer the following construction of claim 58.

Initially, I note for clarity, that claim 58 as reproduced in the appendix of the Brief, appears to contain a typographical error. Specifically, the term "sequence" as it occurs in the phrase "including sequence selected from the group consisting of...." should read "sequences." See e.g., Paper received October 23, 2001, page 3, wherein claim 58 was first introduced into the record and read "... including sequences selected from the group consisting of...." It appears that this typographical error was introduced into the record on December 29, 2003, when appellants submitted an amendment to add the final clause of the claim as it now appears before us on appeal.[6] Nevertheless, I agree with the majority's interpretation of the phrase "including sequence[s] selected from the group consisting of..." to mean "at least one" sequence must be selected from the recited group. Supra, page 3.

Therefore, as I understand it, the method of claim 58 is drawn to a method of identifying a nucleotide sequence. This method comprises comparing a target sequence to a sequence stored on a computer readable media[7], e.g., a CD-ROM disc. Therefore, implicitly, if a sequence other than that required by appellants' claimed

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[6] In the event of further prosecution, I encourage the examiner to clarify this issue.

[7] For clarity, I note that appellants define the term "computer readable medium" at page 37 of their specification as,

> any medium that can be read and accessed directly by a computer. Such media include, but are not limited to: magnetic storage media, such as floppy discs, hard disc, storage medium, and magnetic tape; optical storage media such as CD-ROM; electrical storage media such as RAM or ROM; optical scanner readable medium such as printed paper; and hybrids of these categories such as magnetic/optical storage media.

method is stored on the computer readable media, the claimed method cannot be performed. In this regard, claim 58 requires the computer readable media to have recorded thereon 100 nucleotide sequences, wherein "at least one" is selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof. The last clause of the method set forth in claim 58 requires that the method identify whether the target sequence is present in the sequences recorded on the computer readable media.

Against this backdrop, I now consider the merits of appellants' claimed invention.

II. In vitro versus in silico:

To begin, it may be helpful to take a step back and consider appellants' claimed invention under a different light. Particularly, out of and away from the in silico environment of a computerized process and in terms of an in vitro, "wet chemistry", process. With this in mind, instead of having sequences recorded on a computer readable medium, we have a 100 well plate with one nucleic acid molecule present in each well, wherein at least one of the nucleic acid molecules has a sequence that is selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof. In this regard, the method would be to add a target nucleic acid molecule to each of the 100 wells on the plate[8], allow a hybridization reaction to

[8] In this regard, the nucleic acid molecules function as hybridization partners for a target nucleic acid molecule having a complimentary sequence. Accordingly, if nucleic acid molecules other than those that are specifically recited are used, the method will not produce the stated result - to identify whether the target nucleic acid is present among the sequences on the 100 well plate, which includes at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

take place under appropriate conditions and then after appropriate washing conditions, identify if the target sequence hybridized to any of the nucleic acid sequences on the plate, thereby identifying said target sequence as being present on the plate.

In my opinion, under the foregoing scenario, the examiner and the majority would be hard pressed to give little patentable weight to the specific sequences recited in method. Likewise, if the specific nucleic acid molecules were not known in the art prior to appellants' filing date, the examiner and the majority would be hard pressed to maintain an obviousness rejection, over a prior art reference that taught the same method but used different nucleic acid molecules. In this respect, the foregoing scenario is analogous to In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995). In Ochiai, the claims were directed to a method of making a novel and nonobvious product, from a novel and nonobvious starting material, via a standard chemical reaction. See id. at 1567, 37 USPQ2d at 1129. The examiner rejected the claimed method and the Board affirmed, on the basis that

> [t]he process steps, "introducing" A into AB or "reacting" A with B are standard processes used by practitioners in the prior art for reacting similar A moieties with the same B moiety. We are in agreement with the examiner that there is nothing unobvious in the particular process chosen and claimed by the appellants.

Id. at 1569, 37 USPQ2d at 1130 (emphasis in original).

The Federal Circuit reversed, because the PTO had impermissibly ignored limitations of the claimed method in evaluating its patentability over the prior art. "The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'" Id.

at 1569, 37 USPQ2d at 1131. The court noted that

> [t]he process invention Ochiai recites in claim 6 specifically requires use of none other than its new, nonobvious acid as one of the starting materials. One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6. In other words, it would not have been obvious to those of ordinary skill in the art to choose the particular acid of claim 6 as an acylating agent for the known amine for the simple reason that the particular acid was unknown but for Ochiai's disclosure. . . . As one of our predecessor courts had occasion to observe, in a case involving a highly analogous set of facts, "one cannot choose from the unknown." Mancy, 499 F.2d [1289,] 1293, 182 USPQ [303,] 306 [(CCPA 1974)].

Id. To paraphrase the Ochiai court, it would not have been obvious to a person of ordinary skill in the art at the time the invention was made to select a nucleic acid molecule having a sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, for the simple reason that these particular nucleic acids (defined by SEQ ID NO.), were unknown prior to appellants' disclosure.

On this record, the majority recognizes (supra, page 3), "[t]he examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905...." Stated differently, but for appellants' disclosure, the recited sequences were new and unobvious. In this regard, the majority concedes (supra, page 9), "[a]ppellants have discovered what are apparently several thousand new DNA sequences from E. nidulans. They are entitled to patent the DNAs having those sequences (assuming the DNAs meet all of the statutory requirements)." Nevertheless, despite the examiner and majority's recognition that the recited sequences were not known in the art, prior to appellants' filing date, an obviousness rejection is sustained

over a reference that teaches the claimed process using different nucleotide sequences. Accordingly, I am unable to ratify the majority's decision with the law as understand it.

In essence, all that appellants have done is take a method of identifying a target sequence out of and away from an in vitro environment and place it in silico. As I understand the majority's opinion, by placing the method in silico, the functional relationship between the recited nucleic acid molecules, identified by SEQ ID NOs., and the remaining elements of the claimed method is lost. In my opinion, the facts on this record do not support this conclusion.

III. Statutory subject matter:

Upon consideration of the majority's opinion, it appears that the majority has excised the recited sequences from appellants' claimed method and reconstructed appellants' method to be something that it is not. As a result, the majority enters into a discussion of the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Guidelines)[9], 1300 Off. Gaz. Pat. Office 142 (November 22, 2005), and In re Warmerdam, 33 F.3d 1354, 31 USPQ2d 1754 (Fed Cir. 1994)[10]. To be clear, however, there is no dispute on the record before us on this

[9] As set forth on page 142, column 2, second full paragraph of the Interim Guidelines, "[t]he principal objective of these guidelines is to assist examiners in determining, on a case-by-case basis, whether a claimed invention falls within a judicial exception to statutory subject matter ... or whether it is a practical application of a judicial exception to statutory subject matter."

[10] In Warmerdam, the court held that claims reciting a method for creating a data structure which controlled the motion of objects did not constitute patent eligible subject matter.

appeal as to whether appellants' claimed method is patent eligible subject matter.[11] Since the issue as to whether the claimed invention is patent eligible subject matter is not before us I will not discuss this issue, except to highlight what I consider to be the majority's incorrect interpretation of appellants' claimed invention.

According to the majority (supra, page 8), "the SEQ ID NOs appear to be used merely as inputs for a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database." Contrary, to the majority's assertion, the claimed invention is not "a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database." Instead, the claimed invention is a method of identifying a nucleotide sequence. While the claimed method comprises a comparison step, the claimed result of the method is to identify said target sequence as being present in the computer readable medium.

Further, even if the majority is correct in that the specific sequences recited in appellants' claim are simply data elements for use with a computer program that calculates the degree of similarity between a target sequence and each of the data elements, the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Guidelines), 1300 Off. Gaz. Pat. Office 142 (November

[11] At best, during prosecution, the examiner questioned the utility of appellants' claimed invention under 35 U.S.C. §§ 101 and 112, first paragraph, and invited appellants to "identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention." Office Action, mailed October 6, 2003, page 4. In response, appellants directed the examiner attention, inter alia, to the "disclosed use of the claimed methods ... in the detection of the presence, absence or level of an organism, for example E. nidulans, in a given sample. See, e.g. page 37, lines 7 through 9 and page 30, lines 19 through 21." Response, received December 29, 2003, page 9; Accord, Brief, pages 6-9. As set forth on page 6 of the Answer, the examiner subsequently withdrew the rejection under 35 U.S.C. §§ 101 and 112, first paragraph.

22, 2005), states (page 151, citation omitted), "'functional descriptive material' consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of 'data structure' is 'a physical or logical relationship among data elements, designed to support specific data manipulation functions.' ...)." Thus, it would appear, that even if the claimed database of sequences is used merely as inputs for a computer program, it would appear to fulfill the requirements of "functional descriptive material" as set forth in the Interim Guidelines.

However, faced with legal precedent and Interim Guidelines that fail to support their position, the majority introduces a music analogy to emphasize their point, and further disassociate the sequences set forth in appellants' claim from the underlying method. In this regard, the majority asserts (supra, n. 3), "MP3 files encoding 'America the Beautiful' and 'Yankee Doodle Dandy,' respectively, will cause a computer's speaker to output different songs, yet music is a paradigmatic nonfunctional descriptive material." According to the majority, their findings are consistent with the USPTO's recently announced Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Guidelines), 1300 Off. Gaz. Pat. Office 142 (November 22, 2005), particularly, page 151, "'Nonfunctional descriptive material' includes but is not limited to music, literary works and a compilation or mere arrangement of data." In my opinion, this analysis is not consistent with the facts in this case.

For the majority's analogy to be consistent with this case appellants' claimed invention would be drawn to a compilation of sequences on a CD-Rom disc.[12] This is, however, not the invention before us on appeal. Instead, appellants' claimed method is drawn to a method wherein a computer program is used to compare a target sequence with a database of sequences to identify whether the target sequence is present in the database of sequences. To use the majority's music analogy, the Interim Guidelines, provide an example that, in my opinion, is more on point with appellants' claimed invention than the analogy provided by the majority. Specifically, the Interim Guidelines state (page 152)

> a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process.

Similarly, appellants' claimed method is drawn to a method wherein a computer program compares a target sequence to sequences recorded on a computer readable medium, and upon the conclusion of this comparison identifies whether the target sequence is present among the sequences recorded on the computer readable medium. In my opinion, this defines a functional interrelationship among the data and the computing processes performed when utilizing that data. Accordingly, contrary to

[12] Note, for example, that this was the subject matter of now cancelled claim 29, which was drawn to a "[c]omputer readable medium having recorded thereon at least 100 of the nucleotide sequences depicted in SEQ ID NO: 16207 through SEQ ID NO: 27905 or complements thereof." In the First Office Action on the Merits (mailed May 23, 2001, page 3), the examiner rejected claim 29 under 35 U.S.C. § 101, as drawn to non-statutory subject matter. In response appellants canceled the claim. Response, received October 23, 2001, page 2.

the majority's assertion, it is my opinion that the Interim Guidelines do not support their position.

IV. Functional versus non-functional descriptive material:

According to claim 58, if a target sequence has a sequence defined by one of appellants' recited sequences (e.g., SEQ ID NO: 16207), the claimed method will identify the target sequence as being present in the computer readable medium only if appellants' specifically recited sequence (e.g., SEQ ID NO: 16207), is present among the sequences recorded on the computer readable media. In this regard, I note, there is no evidence on this record that the claimed method can be practiced without the use of the sequences required by appellants' claimed method. Thus, it would appear that the sequences recited in appellants' claimed invention are functionally related to the method, without which the method will not function as claimed.

There is no evidence on this record that any of the sequences identified as SEQ ID NO: 16207 through SEQ ID NO: 27905, were known in the art prior to appellants' filing date.[13] According to appellants' specification (page 4), the sequences set forth in SEQ ID NO: 16207 through SEQ ID NO: 27905 are "genes or partial genes of the E. nidulans genome." In this regard, I note that appellants' specification discloses (page 30), "one or more of the agents of the present invention may be used to detect[ ] the presence, absence or level of ... E. nidulans in a sample." Therefore, as I understand it, the method of claim 58 can be used to detect the presence, absence or level of E.

[13] As the majority points out (supra, page 3), "The examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905...."

nidulans in a sample, by identifying whether a target sequence obtained from a sample is present in the sequences recorded on the computer readable medium. There is no evidence on this record that the claimed method would be able to detect E. nidulans in a sample without appellants' recited sequences.

Nevertheless, in contrast to the foregoing discussion, the majority finds (supra, page 1), "the obviousness of the claimed method does not depend on which sequences are being compared." According to the majority (supra, page 8), "the recited sequences are not related to the computer system carrying out the comparison because the computer compares a target sequence to a database the same way regardless of whether the database includes any of SEQ ID NOs 16207 to 27905: the SEQ ID NOs and the computer do not depend on each other for their function." I agree with the majority, that a particular computer program[14] that is used to compare sequences (e.g., BLASTIN), will compare a target sequence to a database the same way regardless of whether the database includes the sequences required by appellants' claimed method. There is, however, no evidence on this record to suggest that one practicing the method

[14] According to appellants' specification (page 38, lines 13-15), "[c]omputer software is publicly available which allows a skilled artisan to access sequence information provided in a computer readable medium." In addition, Rodriguez-Tomé teach (page 7, column 1, lines 38-41), "the EBI [(European Bioinformatics Institute)] maintains a repository of biology related software on its network servers. This software is also distributed once a year on CD-ROM." Further, I note that claim 58 does not require the use of any particular means for performing the comparison. Therefore, as disclosed in appellants' specification, and taught by Rodriguez-Tomé, methods of identifying a nucleotide sequence by comparing a target sequence to a sequence stored in computer readable medium was known in the art prior to the date of appellants' claimed invention. As the majority points out (supra, bridging paragraph, pages 3-4), there is no dispute on this record that computer programs for comparing sequences were known in the art prior to appellants' filing date.

of claim 58 could obtain the same result[15] required by the method, without using the new and unobvious sequences required by the claim. Therefore, I disagree with the majority's assertion (supra, page 1), "the obviousness of the method does not depend on which sequences are being compared."[16]

I disagree with the majority's characterization of the claimed sequences as non-functional descriptive material. Supra, page 8. As appellants point out (Reply Brief, page 4), "[t]he claimed methods would not achieve their purposes (identification, detection or ranking) without the sequences recorded on a computer readable medium. ... As such, the sequences are functionally related to the computer readable medium and therefore must be considered in the obviousness determination." I agree.

Nevertheless, the majority relies on Ngai, to support their position that the sequences set forth in appellants' claimed method are non-functional descriptive material. Supra, pages 8-9. In my opinion, Ngai does not support the majority's conclusion on the facts of this record. In Ngai, the claim[17] at issue was drawn to a kit for normalizing and amplifying an RNA population. Ngai's kit comprised two components:

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[15] Identifying whether the target sequence is present among the sequences specifically recited in appellants' claimed invention. Thus, contrary to the majority's assertion the SEQ ID NOs and the computer [program] do depend on each other for their function. The computer program would not be able to identify whether a target sequence is among the new and unobvious sequences set forth in appellants' claimed invention if those sequences are not present in the "database".

[16] See, In re Spormann, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966), "[o]bviousness cannot be predicated on what is unknown." Cf. In re Lowry, 32 F.3d 1579, 1583, 32 USPQ2d 1031, 1034-35 (Fed. Cir. 1994), quoting In re Bernhart, 417 F.2d 1395, 1400, 163 USPQ 611, 616 (CCPA 1969) ("if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged. The fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not been changed.").

[17] Claim 19 was the only claim on appeal in Ngai. During prosecution, the examiner indicated that Ngai's method claims, claims 1-18, were allowable. In addition, the Board reversed the examiner's obviousness rejection of Ngai's only remaining claim, claim 20, which was drawn to a kit. Accordingly, claim 20 was not at issue on appeal.

(1) a product (e.g., a buffer), and (2) instructions for the use of the product. In Ngai, the prior art relied upon in the anticipation rejection taught a kit comprising a buffer and instructions[18]. Ngai, at 1337, 70 USPQ2d at 1863. Accordingly, in Ngai, "the only difference between the prior art and [Ngai's] claim 19 is the content of the instructions." Id. On the facts in Ngai, the court found, "[a]ll that the printed matter does is teach a new use for an existing product." Ngai, at 1339, 70 USPQ2d at 1864. In this regard, it has long be held that a claim to an otherwise old composition cannot be distinguished from the prior art simply by asserting a new use for the composition. See e.g., In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) ("terms [that] merely set forth the intended use for ... an otherwise old composition ... do not differentiate the claimed composition from those known in the prior art.").

In contrast to Ngai, on this record, the majority admits (supra, n. 3), "the results of comparing a target sequence to a database may[19] change depending on which sequences are included in the database." Stated differently, in the method before us on this record, the claimed method will provide a different result if the sequences set forth in appellants' claims are not used. Accordingly, I disagree with the majority's conclusion (supra, page 8), "[t]he SEQ ID NOs recited in claim 58 are analogous to the instructions in In re Ngai." Where in Ngai, the instructions did not affect the product, here appellants' recited sequences, play a critical role in the claimed method, and will directly affect the result of the claimed method.

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[18] As the majority points out (supra, page 6), the instructions in the prior art differed from Ngai's instructions.

[19] While the majority uses the term "may", there is no evidence on this record that the same result would be obtained using sequences other than those required by appellants' claimed invention.

Further, while the majority agrees that appellants' claimed method will lead to a different result if the claimed sequence is not used, the majority dismisses this seemingly critical fact by "classifying" the sequences recited in claim 58 as non-functional descriptive material. Supra, page 8. To emphasize this point the majority attempts to distinguish the sequences recorded on a computer readable medium from the "data structures" in In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994). In this regard, the majority finds (supra, pages 7-8), in contrast to Lowry,

> there is no evidence that SEQ ID NOs 16207 to 27905 functionally affect the process of comparing a target sequence to a database. There is no evidence, for example, that these SEQ ID NOs interact with other computer hardware or software to affect the efficiency or accuracy or any other characteristic of the comparison. ... [T]he SEQ ID NOs appear to be used merely as inputs for a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database. ... [T]he specific SEQ ID NOs recited in the claims do not affect how the method of the prior art is performed....

The majority's argument, however, appears to be somewhat inconsistent with their other findings. On one hand the majority finds (supra, n. 3), "[o]f course, the results of comparing a target sequence to a database may change depending on which sequences are included in the database." On the other hand, the majority finds (supra, pages 7-8, footnote omitted), "[t]here is no evidence that SEQ ID NOs 16207 to 27905 functionally affect the process of comparing a target sequence to a database ... the specific SEQ ID NOs recited in the claims do not affect how the method of the prior art is performed – the method reasonable appears to be carried out the same way regardless of which specific sequences are included in the database." It's hard to imagine how the results obtained from the claimed method could change depending on which sequences are included in the database, in the absence of a functional

relationship between the recited sequences and the other elements of the claimed method.

Further, as discussed above, even if the majority is correct in that the specific sequences recited in appellants' claim are simply data elements for use with a computer program that calculates the degree of similarity between a target sequence and each of the data elements, the Interim Guidelines states (page 151, citation omitted), "'functional descriptive material' consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of 'data structure' is 'a physical or logical relationship among data elements, designed to support specific data manipulation functions.' ...)." In the context of appellants' claimed invention, the sequences recorded on the computer readable medium are essentially the electronic equivalent to a "hybridization partner" for the "target sequence." Thus, it would appear, that even if the claimed database of sequences is used merely as inputs for a computer program, it would appear to fulfill the requirements of "functional descriptive material" as set forth in the Interim Guidelines.

Accordingly, it is my opinion that the precedent relied upon by the majority fails to support their finding that the sequences as recited in appellants' claimed invention should be classified as "non-functional descriptive material," and therefore given no patentable weight in the context of appellants' claimed invention.

V. Public policy considerations:

I recognize the majority's concern (supra, page 9), "if we were to adopt Appellants' position, anyone could continue patenting methods of analyzing genetic

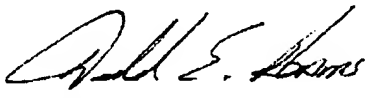
sequence data – or any other data, for that matter – provided that they included at least one new DNA sequence or other datum in a known database." I find the majority's concern troubling for two reasons. First, as our appellate reviewing court explained in In re Fisher, 421 F.3d 1365, 1378, 76 USPQ2D 1225, 1235 (Fed. Cir. 2005), such public policy considerations are not to "affect the determination of whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. Second, as I understand the majority's concern, anyone could continue to advance the useful arts by seeking patent protection on methods of analyzing genetic sequence data using previously unknown DNA sequences[20]. While the majority's argument is based on a similar statement in Ngai, it must be emphasized that the court's statement in Ngai was directed at the continued patenting of a known product, simply by adding a new instruction sheet to the product. This is not same as the method before us on this record. There is no evidence on this record that claimed method will produce the same result if sequences other than those recited in appellants' claim are used. To the contrary, the majority recognizes that a different result will be obtained if appellants' sequences are not used. Supra, n. 3. Accordingly, it is unclear how the majority can conclude that the sequences are not functionally related to the remaining elements of the method. Cf. Gulack and Ngai. It is also unclear how the majority can find the claimed method to be obvious when the sequences recited in appellants claim are new and non-obvious. Cf. Ochiai.

[20] According to the majority (supra, page 9), appellants are entitled to patent the new DNA sequences from E. nidulans that they have discovered "but they are not entitled to patent a known method of sequence comparison by merely including at least one novel DNA sequence in a database." In this regard, the majority notes (supra, page 3), "[t]he examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905...."

VI. Conclusion:

In my opinion, the sequences recited in appellants' claim are functionally related to the remaining elements of the method. There is no evidence on this record that the sequences recited in appellants' claim where known or obvious to one of ordinary skill in the art at the time of appellants' invention. Therefore, giving weight to the sequences as recited in appellants' method, the claimed method is not taught or suggested by Rodriguez-Tomé, the only reference relied upon in the rejection of record.

Accordingly, I would reverse the rejection of claims 58-72 under 35 U.S.C. § 103 as being unpatentable over Rodriguez-Tomé.



Donald E. Adams
Administrative Patent Judge

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